Application No. 09/975,565 Group Art Unit: 1618

Amendment Dated: 12/15/05

## **AMENDMENTS TO THE CLAIMS**

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of claims:

1. (Currently amended) A pharmaceutical composition comprising:

a microparticle having an mean particle size of between about 1.0  $\mu m$ , said microparticle comprising:

a polymeric support material in which a substance can be dispersed, wherein the support material comprises at least about 50% w/w of at least one homopolymer with a repeat unit according to Formula (I):

wherein

 $R_1$  represents a  $C_1$ - $C_6$  alkyl group or a group  $(CH_2)_m$ - $COOR_3$  wherein m is an integer from 1 to 5 and  $R_3$  is a  $C_1$ - $C_6$  alkyl group,  $R_1$  and  $R_3$  being the same or different;

 $R_2$  represents a  $C_1$ - $C_6$  alkyl group the same or different from  $R_1$  and  $R_3$ ; n is an integer from 1 to 5; and

at least one therapeutic agent that is encapsulated or dispersed in the polymeric support material of the microparticle.

- 2. (Original) A pharmaceutical composition according to claim 1 wherein:  $R_1$  and  $R_2$  are independently chosen  $C_1$ - $C_6$  alkyl groups; and n is 1.
- 3. (Original) A pharmaceutical composition according to claim 1 wherein: the stated homopolymer comprising repeat units according to Formula (I) wherein  $R_1$  and  $R_2$  are ethyl groups; and

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n=1.

4. (Currently amended) A pharmaceutical composition according to claim 3, wherein the composition being is obtained by a single emulsification process.

5. (Previously Presented) A pharmaceutical composition according to any one of claims 1 to 4 wherein the support material comprises:

from about 90 to about 99.5% by weight of a homopolymer as defined in claim 1; and from about 0.5 to about 10% by weight of a polymer additive.

- 6. (Original) A pharmaceutical composition according to claim 5 wherein the polymer additive comprises at least one of polyethyleneoxide, polyvinylalcohol, polyvinylpyrrolidone, poly(N-2-hydroxypropyl methacrylamide), polyhydroxyethylmethacrylate, hydrophilic poly(aminoacid) such as polylysine or polysaccharide.
- 7. (Previously Presented) A pharmaceutical composition according to claim 5 wherein the polymer additive is a polyvinylalcohol.
- 8. (Previously Presented) A pharmaceutical composition according to claim 1 wherein the dispersed substance is hydrophobic.
- 9. (Previously Presented) A pharmaceutical composition according to claim 1 wherein the dispersed substance is a therapeutic agent that requires a solvation vehicle for administration.
- 10. (Previously Presented) A pharmaceutical composition according to claim 1 wherein the dispersed substance is hydrophylic.
- 11. (Previously Presented) A pharmaceutical composition according to claim 1, wherein the dispersed substance is a therapeutic agent.

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12. (Withdrawn) A pharmaceutical composition according to claim 1, wherein the dispersed substance is a peptide or polypeptide.

- 13. (Withdrawn) A pharmaceutical composition according to claim 1 wherein the dispersed substance is a protein.
- 14. (Currently amended) A pharmaceutical composition according to any one of claim 1 wherein the dispersed substance is a bioactive molecule such as a drug, a therapeutic agent, an anticancer agent, a gene therapy agent, a plasmid DNA, a protein, an enzyme, a peptide, a radionuclide, a protein inhibitor, an analgesic, an anti-inflamatory agent, an antibiotic, an antiviral agent, an antineoplastic agent, a pyrimidine, purine or folic acid analog, an cytotoxic agent, an immunomodulator, a hormone, an antibody or a painkiller.
- 15. (Previously Presented) The pharmaceutical composition of Claim 14 wherein the pyrimidine analog is fluorouracil (5-FU).
- 16. (Previously Presented) A pharmaceutical composition according to claim 1 wherein the dispersed substance is a bioactive molecule such as an anticancer agent or a gene therapy agent.
- 17. (Currently amended) A pharmaceutical composition according to elaims claim 1 wherein the dispersed substance is a therapeutic agent for treating or reducing the severity of a urological disease or disorder.
- 18. (Previously Presented) A pharmaceutical composition according to claim 1 wherein the dispersed substance is a therapeutic agent for bladder cancer.
- 19. (Currently amended) A pharmaceutical composition according to any one of claim 1, wherein the dispersed substance is a taxane.

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20. (Original) A pharmaceutical composition according to claim 19, wherein the taxane is paclitaxel, docetaxel (Taxotere®) or taxol®.

21-36. (Cancelled).

37. (Previously Presented) A method for treating a urological disease or disorder comprising:

administering intravesically a microparticle having a mean particle size of between about  $1.0~\mu m$  and  $100~\mu m$  with one or more encapsulated therapeutic agents to the lumen of the bladder;

contacting the particles to the surface of the mucosa,

releasing the encapsulated therapeutic agent in a controlled manner to treat the urological disease or disorder.

- 38. (Original) A method according to claim 37 wherein the microparticle comprises a poly(methylidene malonate 2.1.2) polymer support material.
- 39. (Original) A method according to claim 37 wherein the urological disorder is a cancer and the microparticle encapsulated therapeutic agent is an anticancer agent.
- 40. (Previously Presented) A method according to claim 37 wherein the anticancer agent is a taxane.
- 41. (Currently amended) A method according to any to-claim 40 wherein the taxane is paclitaxel, docetaxel (Taxotere®) or taxol®.
- 42. (Previously Presented) A method according to claim 37, wherein microparticles with encapsulated paclitaxel are used for intravesical chemotherapy of bladder cancer.

43-51. (Cancelled).

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52. (Previously Presented) The pharmaceutical composition of claim 1, wherein the microparticle has a mean particle size of between about 1.0  $\mu$ m and 20  $\mu$ m.

53. (Previously Presented) The method of claim 37, wherein the microparticle has a mean particle size of between about 1.0  $\mu$ m and 20  $\mu$ m.